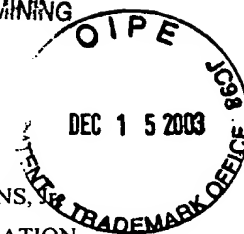


Docket No. 218025US34PCT

RESPONSE UNDER 37 CFR 1.116-  
EXPEDITED PROCEDURE EXAMINING  
GROUP 1623



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Silvio DE FLORA, et al.

SERIAL NO: 09/125,022

GAU: 1623

FILED: November 24, 1998

EXAMINER: Howard V. OWENS, Jr.

FOR: PHARMACEUTICAL COMPOSITION ENABLING TO INHIBIT CANCER METASTASIS FORMATION  
CONTAINING N-ACETYL-CYSTEINE AND DOXORUBICIN

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

12/17/2003 MDANTE1 00000062 09125022

03 FC:1806

180.00 DP

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Respectfully submitted,

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Re: In re Application of: Silvio DE FLORA, et al.  
U.S. Application Serial No.: 09/125,022  
Filing Date: November 24, 1998  
For: PHARMACEUTICAL COMPOSITION ENABLING  
TO INHIBIT CANCER METASTASIS FORMATION  
CONTAINING N-ACETYL-CYSTEINE AND  
DOXORUBICIN  
Group Art Unit: 1623  
Examiner: Howard V. OWENS, Jr.

**STATEMENT OF RELEVANCY**

The references filed herewith are relative to the use of B16 cells for testing efficacy of drugs against solid tumors. These articles indicate that the B-16 tumor line is the appropriate tumor cell line for testing effects of drugs on metastases.



Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 218025US34PCT		SERIAL NO. 09/125,022	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Silvio DE FLORA, et al.			
				FILING DATE November 24, 1998		GROUP 1623	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	AO						
	AP						
	AQ						
	AR						
	AS						
	AT						
	AU						
	AV						
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	Griswold, "Consideration of the Subcutaneously Implanted B16 Melanoma as a Screening Model for Potential Anticancer Agents," Cancer Chemotherapy Reports, Part 2, Vol. 3, No. 1 (November 1972), pp. 315-324					
	AX	Goldin et al., "Screening at the National Cancer Institute," National Cancer Institute Monograph 45 (March 1977), DHEW Publication No. (NIH) 76-1037, pp. 37-48					
	AY	Carter et al., "Experimental Models and Their Clinical Correlations," National Cancer Institute Monograph: USA-USSR, National Cancer Institute Monograph 45, (March 1977) DHEW Publication No. (NIH) 76-1037, pp. 63-74					
	AZ					<input type="checkbox"/> Additional References sheet(s) attached	
Examiner Howard V. OWENS, Jr.					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							